

Appl. No. 09/558,465
Any. Docket No. 7546M
Amdt. dated July 23, 2004
Reply to Office Action of January 26, 2004
Customer No. 27752

REMARKS

Claims 1 - 34 are pending in the present application. No additional claims fee is believed to be due.

Invention Synopsis

The present invention discloses a shampoo composition comprising from about 5% to about 50%, by weight, of an anionic surfactant; from about 0.01% to about 10%, by weight, of a non-volatile conditioning agent; from about 0.1% to about 4%, by weight, of an anti-dandruff particulate; from about 0.02% to about 5%, by weight, of a cationic polymer; water, from about 0.1% to about 10%, by weight of the composition, of a suspending agent; wherein said composition has a bioavailability/coverage index value, of at least about 1.25; has a first conditioning index value, of less than or equal to about 1.0; has a second conditioning index value, of at least about 1.5; and has a minimal inhibitory concentration index value, of at least about 0.125.

The Rejection under 35 U.S.C. 103(a) over Ramachandran et al in view of Cardin et al.

Claims 1-9 and 11-34 have been rejected under 35 U.S.C. as being unpatentable over Ramachandran et al (WO96/29983) in view of Cardin et al (US 5,104,645). The Examiner has asserted that it would have been obvious to include the anti-dandruff of Cardin in the teachings or Ramachandran because Cardin teaches anti-dandruff shampoos comprising 1-hydroxy-2-pyridinethione salt in platelet particle form having a specified particle size and similarly Ramachandran teaches shampoo compositions comprising therapeutics agents (i.e. ketoconazole, ZPT, etc) in shampoos. The expected result would be an effective antidandruff composition that exhibits increased efficacy. Applicants respectfully traverse this rejection.

Applicants kindly state that in order to establish a prima facie case of obviousness, the Examiner must show that (1) there is some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there is a reasonable expectation of success, and (3) all of the limitations of the claims are taught or suggested in the prior art (M.P.E.P. § 2143).

1) Ramachandran in view of Cardin does not establish a prima facie case of obviousness because they do not teach or suggest all of Applicants' claim limitations. In the present case, and with respect to Claims 1-9 and 11-34, Ramachandran does not teach that the zinc salt of 1-hydroxy-2-pyridinethione in platelet particle form. Further, Ramachandran does not disclose the combination of a cationic polymer with a non-volatile conditioning agent. The conditioning

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agents are listed as one of many possible ingredients in the final shampoo composition. Within the category of conditioning agents, cationic polymer is mentioned in a long list of potential ingredients, none of which is required. The cationic polymer is not included in any of the specific examples, and it is not combined with a conditioning agent.

The possible shampoo formulations that can be devised by selecting items from Ramachandran's optional ingredients number in the hundreds. A shampoo combining an anionic surfactant, a non-volatile conditioning agent, an anti-dandruff particulate, a cationic polymer derivative and water is only one of these hundreds of possible shampoo formulations. There is no embodiment of this combination. In fact, there is no example that includes a cationic polymer.

Cardin teaches 1-hydroxy-2-pyridinethione salt in platelet form. The Examiner asserts that Cardin teaches that the platelet form of pyridine metal salt is combined with any group of specific synergizers in a shampoo matrix, and results in an unexpected substantial improvement in anti-dandruff efficacy. However, Cardin solely teaches that the shampoo's antidandruff efficacy is unexpectedly enhanced. There is no teaching in Cardin that the conditioning efficacy is enhanced. Further, the synergizers that Cardin teaches, such as polyethylene glycol (PEG) and polypropylene glycol (PPG) are known for use in shampoos as viscosity modifiers, not as conditioning agents. Therefore, there is no teaching in Cardin for increased conditioning efficacy, as is surprisingly achieved in the present invention as demonstrated by the first and second conditioning index values. There is no teaching in Cardin of cationic polymers. The present invention has found that the cationic polymers are believed to provide increased anti-dandruff efficacy and increased conditioning to the shampoo compositions.

As further demonstration regarding the rejection under 103 (a), Applicants previously submitted a Declaration of David S Dunlop under 37 C.F.R. 1.132. Applicants respectfully re-submit this declaration which demonstrates that surprisingly not all formulas with similar components met the criteria for the specified and required indexes of the present invention's claims.

Formula A, representative of the present invention, meets the criteria as outlined in the present invention's Claim 1 for bioavailability/coverage index and the second conditioning index. Formula A is representative of the Examples found in the specification on pages 56-57 of the specification comprising Viscasil 300,000, Cetyl Alcohol, Guar Hydroxypropyltrimonium chloride having a molecular weight of about 200,000 from Aqualon, Hydrogenated Polydecene, zinc pyrithione, and surfactants.

Formula B, an example of another conditioning shampoo, meets none of the criteria for the bioavailability/coverage index and the second conditioning index. Applicants would like to

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provide further details with regard to Formula B, as the Examiner has noted that Formula B was cited as being representative of another conditioning composition, and thus was not found to be persuasive. Specifically, Formula B comprises Viscasil 300,000, Cetyl Alcohol, Guar Hydroxypropyltrimonium Chloride (Jaquar C17), Hydrogenated Polydecene, Zinc pyrithione, and surfactants. Therefore, Formula B comprises zinc pyrithione in combination with several conditioning agent, yet fails to achieve both a positive bioavailability index or a second conditioning index. If Examiner would prefer the Applicants to submit a new declaration, in order to provide further description of Example B, Applicants will be happy to provide.

Formula C, which would be representative of a formula similar to that described in Ramachandran et al, does not meet the criteria for the second conditioning index, as required by the present invention. Therefore, Applicants have demonstrated that it is not implicit in the teachings of Ramachandran et al that such index values would be present. The present invention, demonstrates the specific selection of components, in order to achieve a surprising result and benefit. Applicants have surprising found through much investigation and invention, the specific criteria required to meet the specified and distinct index values, as defined and claimed, in order to achieve the surprising benefits of the present invention.

Specifically, the Declaration demonstrates that only Example A, representative of the present invention, demonstrates increased efficacy for the second conditioning index, achieving a second conditioning index value of at least about 1.5. Generally, the higher the index value of the composition, the better its conditioning, due to increased clear hair feel.

With regard to the Examiner's assertion that the Declaration appears to be qualitative rather than quantitative, Applicants respectfully traverse this assertion. For clarification, the terms "Yes" and/or "No" represent that the formula has or has not meet the quantitative value of the index. For Example, Formula A, representative of the present invention, has resulted in a "Yes" for both indexes, and therefore correlates with having a bioavailability/ coverage index of at least about 1.25, and having at a second conditioning index value of at least about 1.5. Applicants were using the Yes or No format in order to simplify for referral, and reveal whether the success criteria for the index value has been met or not. If the Examiner would prefer Applicants to submit a new Declaration with the specific quantitative values, Applicants will be happy to resubmit.

Therefore, Ramachandran in view of Cardin does not teach all of the claim limitations of the present invention and have thus, not established a prima facie case of obviousness.

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2) The Examiner has not provided the requisite motivation to modify or combine either the Ramachandran reference with the Cardin reference so as to obtain Applicants' invention. The Examiner has asserted that the prior art teaches a similar formulation comprising similar ingredients for a related purpose. However, Ramachandran does not disclose the combination of a cationic polymer with a non-volatile conditioning agent. The conditioning agents in Ramachandran are listed as one of many possible ingredients in the final shampoo composition. Within the category of conditioning agents, cationic guar is mentioned in a long list of potential ingredients, none of which is required. The cationic guar is not included in any of the specific examples, and it is not combined with a conditioning agent. The possible shampoo formulations that can be devised by selecting items from Ramachandran's optional ingredients number in the hundreds. A shampoo combining an anionic surfactant, a non-volatile conditioning agent, an antidandruff particulate, a cationic polymer and water is only one of these hundreds of possible shampoo formulations. There is no embodiment of this combination. In fact, there is no example that includes a cationic polymer.

Ramachandran in view of Cardin does not teach a composition wherein one of skill in the art would be lead to the specific selection of components, in order to achieve a surprising result and benefit, with regard to bioavailability/coverage index, first and second conditioning index, and minimal inhibitory concentration index, without undue experimentation. Applicants have surprising found through much investigation and invention, the specific criteria required to meet the specified and distinct index values, as defined and claimed, in order to achieve the surprising benefits of the present invention, as demonstrated by 1.132 Declaration.

One of skill in the art would not have been motivated to combine the teachings of Ramachandran with Cardin, as Cardin is directed toward the combination of 1-hydroxy-2-pyridinethione with a synergizer such as polypropylene glycol or polyethylene glycol. Cardin is directed solely toward enhanced antidandruff efficacy by the incorporation of a synergizer. There is no disclosure in Cardin that would lead one of skill in the art to enhance the conditioning benefits of a composition, which are part of the claim limitations of the present invention.

There is no description in any of the references regarding the relationship between the combination of these specific materials of the present invention and the purpose or benefit of providing a solution to the problem for which the present invention has solved. Thus there is no motivation in the Ramachandran reference to combine it with the Cardin reference and arrive at the benefit of the present invention.

In summary, Ramachandran in view of Cardin does not establish a prima facie case of obviousness because all of the limitations of the claims are not taught or suggested in the prior art. Secondly, there is no suggestion or motivation to modify the references, as none of the references,

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either alone or in combination, teach, recognize or are for a related purpose when compared to the purpose of the present invention. Therefore, Applicants' contend that the claimed invention is unobvious and that the rejection should be withdrawn.

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 35 U.S.C. 103(a). Early and favorable action in the case is respectfully requested.

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-9 and 11-34.

Respectfully submitted,
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